UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,476	01/21/2004	Steven Bernard	3659-79	9797

23117 7590 07/11/2006

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
DEAK, LESLIE R	
ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,476	BERNARD ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5, 6, 9-13, and 15-28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,494,693 to Sunden.

In the specification and figures, Sunden discloses the device as claimed by applicant. With regard to claims 1-2, 19, 27, and 28, Sunden discloses a pump tube 10 comprising a first end 12A with a first inside diameter (see FIG 2D), a narrow center section of the tube 14 with a minor diameter (see 16 in FIG 2B) narrower than the first diameter that helps to push fluid through the tube during pumping operations(see column 7, lines 28-45). In FIG 2A, Sunden illustrates the narrow section as comprising more than one half of the illustrated tube segment. Sunden further illustrates a tapered tube transition section between the first end and the narrow section (unlabeled, see FIG 2A), and a second end 12B with an inside diameter the same size as end 12A. Sunden discloses that the tube is used to pass sensitive biological materials therethrough, which may include blood (see column 1, lines 23-25).

With regard to claims 5, 16, 17, 21, and 22, Sunden illustrates that all sections of the pump tube comprise substantially the same wall thickness (see FIGS 2B, 2C, 2D).

With regard to claims 6 and 15, 20, Sunden discloses that the inner diameter of the fluid passageway of the reduced diameter pump section may range from 0.1 to 4mm, meeting applicant's claim drawn to a diameter of 0.06in (see column 12, lines 55-67). Sunden further discloses that the outer diameter of the normal diameter, non pump portion of the tube will range from 12-16mm, with the outer diameter of the pump section will range from 2-18mm (see column 13, lines 1-10). Sunden illustrates the outer diameter of the pumping section to be smaller than that of the larger section, meeting the limitations of applicant's claims (see FIGS 2A-2D).

With regard to claims 9-12, 18, 23, 24, and 26, Sunden discloses that first and second ends of the single-lumen tube are attachable to a connector (not shown, see column 7, lines 19-25). Sunden further illustrates that the transition from the wide section to the narrow section is a smooth transition, teaching that abrupt changes in the direction of the tube (such as sharp turns or edges) should be avoided (see FIG 2A, column 7, lines 40-48).

With regard to claims 13 and 25, Sunden discloses that the tube may be manufactured from PTFE, which is a biocompatible polymer (see column 12, lines 8-25).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,494,693 to Sunden in view of US 3,882,862 to Berend.

In the specification and figures, Sunden discloses the device substantially as claimed by applicant (see rejection above). Sunden fails to disclose the exact length of the transition section, tubing lines, or a third section of increased diameter tubing. However, Berend discloses a variable diameter tube for that uses variable lengths and diameters to control the pressure, flow rate, and turbidity of flow in the tube (see column 3, lines 15-56, column 4, lines 1-10). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the extracorporeal tube disclosed by Sunden in the dimensions claimed by applicant, since Berend discloses that such variations in the dimensions of the tube may be used to control flow according to Bernoulli's flow principles, optimizing the flow of blood through the tube.

5. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,494,693 to Sunden in view of US 4,954,055 to Raible.

In the specification and figures, Sunden discloses the device substantially as claimed by applicant (see rejection above). Sunden fails to disclose a segment of increased diameter between the narrow sections of the tube. However, Raible discloses a pump tube with narrow end sections 16, 18, and a center section 20 of increased diameter that provides for less turbulent pumping of blood through the pumping section of the tube (see column 1, lines 20-31, column 2, lines 13-24). Therefore, it would have

been obvious to one having ordinary skill in the art at the time the invention was made to add a small area of increased diameter as disclosed by Raible to the pump tube disclosed by Sunden in order to increase the rate of pumping while decreasing hemolysis, as taught by Raible. With regard to applicant's recitations drawn to the length of the sections of increased diameter with relation to the length of the tube, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05. In the instant case, Raible discloses that the dimensions of the tube, including the length of each section, may be adjusted to accommodate the pump in which the tubing is deployed (see column 4, lines 1-22). Therefore, it would have been obvious to none having ordinary skill in the art at the time the invention was made to form the tube disclosed by Sunden and Raible in the dimensions claimed by applicant in order to fit the desired pumping apparatus.

Response to Arguments

6. Applicant's amendment and arguments filed 20 April 2006 have been entered and considered.

7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant presents new claims 15-28 without any argument as to the specific patentability of the new claims, which are broader in scope than the claims previously

presented for examination. As such, the new claims are rejected above, since the limitations of the new claims are found in the earlier presented, narrower claims.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
29 June 2006